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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,289	03/26/2002	Tomohiro Yamamoto	10059-411US (P260049-01)	9375
570	7590	01/22/2004	EXAMINER	
AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103-7013			NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/089,289

Applicant(s)

YAMAMOTO ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) other (6).
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: IDS's of March 26, 2002 and June 09, 2003.

*Drawings*

1. Figure 9 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Applicant's specification describes Figure 9 as showing prior art (bottom of page 4 and page 11, brief description of Figure 9).

*Claim Objections*

2. Claims 1 and 8 are objected to because of the following informalities:
- a) Claim 1, line 12: -- the -- should be placed before "surface";
  - b) Claim 8, line 3: -- is -- should be placed before "smaller"; and
  - c) Claim 8, line 3: -- the -- should be placed before "thickness".
3. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1: it is not clear whether Applicant intends for a space in the biosensor to encircle the entire filter ("in an area from one end of the filter ... to the other end of the filter ..."), which the last three lines of the claim imply. The Examiner suggests

(i) replacing "from" in line 12 with -- located between --, and

(ii) replacing the second occurrence of "to" in line 13 with -- and --.

Also, antecedent basis should be provided for the two ends of the filter referred to in the last three lines of the claim; and

b) Claim 1: lines 4-7 (the phrase "a cover member .. electrode system,") suggest that the sample solution pathway is *between* the sample supply unit and the electrode system. However, lines 10-11 of the claim state that the sample supply unit is *in* the sample supply pathway.

Note that dependent claims will have the deficiencies of base and intervening claims.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shieh (US 5,779,867).

Addressing claim 1, Shieh '867 teaches a biosensor (abstract), comprising an insulating base plate (**20** in Figures 1B and 1C) an electrode system that is provided on the base plate and has at least a working electrode (**14**) and a counter electrode (**17**), a cover member (**22**) that is combined with the base plate to define a sample solution supply pathway for loading a sample solution from a sample supply unit to the electrode system (**24**), a reaction reagent system including at least an oxidation-reduction enzyme and an electron mediator (**15** and col. 3, ll. 24-33), and a filter (**18**) disposed between the electrode system and the sample supply unit in the sample solution pathway, the biosensor having a space that encircles the surface of the filter in an area located between one end of the filter close to the sample supply unit and the other end of the filter close to the electrode system.

Note

(a) although not directly mentioned as such, TTF and TCNQ are electrode mediators. This may be seen from the abstract and col. 3, ln. 62 – col. 4, ln. 13 of US patent no. 5,522,977, which issued from application no. 08/319,618, which Shieh '867 refers to for further details on TTF and TCNQ (col. 3, ll. 27-33);

(b) “a sample supply unit” may be nothing more than the opening in a plate through which sample flows (page 23, lines 6-7 in the specification), or indeed, just a plate surface (page 18, lines 16-18 in the specification); and

(c) as may be inferred from the biosensor views shown in Figures 1A-C the circumferential surface of the filter is encircled by space.

Addressing claim 2, as seen from Figures 1B and 1C the cover member is disposed above the base plate and the sample solution supply pathway starts from the sample supply unit provided on the base plate.

Addressing claim 3, as seen from Figures 1B and 1C the supply unit is located above the front side of the electrode system. Note that a “side” of the electrode can be broadly interpreted to be any surface of the electrode since the claim does not make reference to any other dimensional aspects of the electrode than its ends;

Addressing claim 6, as seen from Figures 1B and 1C "said supply solution pathway is disposed in a direction of gravity from said sample supply unit provided on said cover member."

Addressing claim 7, as seen from Figures 1B and 1C "said sample supply unit is located above said electrode system."

***Allowable Subject Matter***

7. Claims 4, 5, and 8-14 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter:

- a) Claims 4 and 8: in Shieh '867 the space has essentially infinite width, as the space encircling the circumference of the filter is not bounded;
- b) Claim 5 depends from allowable claim 4;
- c) Claim 9 depends from claims 5 or 8, which are allowable; and
- d) Claims 10-14 depend directly or indirectly from allowable claim 9.



Art Unit: 1753

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1042.

*Alex Noguerola*

Alex Noguerola

01/12/04

Primary Examiner

TC 1753